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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,004	01/03/2001	Marc Feldmann	65019-DA-PCT-US/JPW/AJM	2757

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03/12/2002

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EXAMINER

GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/12/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

Applicant(s)

09/754004

FELDMAN

Examiner

Art Unit

GAMBEL

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

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DETAILED ACTION

1. The instant application is in compliance with the sequence rules.
2. Claims 1-38 are pending.
3. Prior to setting forth the restriction requirement, it is pointed out that the claims are drawn to patentably distinct methods which rely upon TNF α antagonists that do not comprise a common structural feature that contributes to their common utility and, in turn, rely upon distinct products. The methods rely upon TNF-specific antibodies, p55TNF α receptors, p75TNF α receptors, pentoxifylline, rolipram, thalidomide, tenidap, A2b adenosine receptor agonist and a A2b adenosine receptor enhancer. These TNF α antagonists differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. Therefore, the restriction will be set forth for each of the various groups, irrespective of the format of the claims, because these are not proper species.
4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-6, 11-19, 24-38, drawn to methods of treating TNF-mediated diseases with methotrexate and TNF-specific antibodies, classified in Class 424, subclass 130.1.
 - II. Claims 1-6, 20-23, 24-38, drawn to methods of treating TNF-mediated diseases with methotrexate and p55TNF α receptors, classified in Class 514, subclass 8.
 - III. Claims 1-6, 20-23, 24-38, drawn to methods of treating TNF-mediated diseases with methotrexate and p75TNF α receptors, classified in Class 514, subclass 8.
 - IV. Claims 1-8, 24-38, drawn to methods of treating TNF-mediated diseases with methotrexate and pentoxifylline, classified in Class 424, subclass 450.
 - V. Claims 1-8, 24-38, drawn to methods of treating TNF-mediated diseases with methotrexate and rolipram, classified in Class 514, subclass 46.
 - VI. Claims 1-6, 9, 24-38, drawn to methods of treating TNF-mediated diseases with methotrexate and thalidomide, classified in Class 514, subclass 221.
 - VII. Claims 1-6, 9, 24-38, drawn to methods of treating TNF-mediated diseases with methotrexate and tenidap, classified in Class 424, subclass 400.
 - VIII. Claims 1-6, 10, 24-38, drawn to methods of treating TNF-mediated diseases with methotrexate and A2b adenosine receptor agonists and enhancers, classified in Class 514, subclass 46.

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5. Inventions I - VIII are different methods, which require different ingredients and process steps. These methods rely upon TNF-specific antibodies, p55TNF α receptors, p75TNF α receptors, pentoxifylline, rolipram, thalidomide, tenidap, A2b adenosine receptor agonist and a A2b adenosine receptor enhancer. These TNF α antagonists differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable.

6. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-VIII is not required for any other group from Groups I-VIII and Groups I-VIII have acquired a separate status in the art because the searches are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

7. This application contains claims directed to the following patentably distinct species of the claimed Groups I- VIII: wherein the TNF-mediate disease is:

- A) an autoimmune disease,
- B) acute or chronic disease,
- C) inflammatory disease, or
- D) neurodegenerative disease.

It is noted that these categories recited in the claims are overlapping. Applicant should elect a specific category of disease (e.g. autoimmune disease or neurodegenerative disease) that would be readily understood by the ordinary artisan (see pages 6-8 of the instant specification)

AND, in addition,

applicant should elect a specific disease or disorder (e.g. rheumatoid arthritis) (see pages 6-8 of the instant specification).

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic, for example.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
March 7, 2002